

No. D-307-CV-2020-02629

Plaintiff,)
v.)

STERIGENICS U.S., LLC, SOTERA HEALTH
HOLDINGS, LLC, SOTERA HEALTH LLC,
AND SOTERA HEALTH COMPANY,

Defendants.)

**ANSWER AND DEFENSES OF STERIGENICS U.S., LLC
TO PLAINTIFF'S COMPLAINT**

Pursuant to the New Mexico Rules of Civil Procedure for the District Courts, NMRA § 1-001, *et seq.*, Defendant Sterigenics U.S., LLC (“Sterigenics U.S.”), hereby files its Answer and Defenses as follows:

ANSWER

Sterigenics U.S., by and through its undersigned counsel, hereby responds to the allegations contained in the individually numbered Paragraphs of Plaintiff's Complaint against it in the numbered paragraphs below.¹ Sterigenics U.S. hereby denies any allegation that is not specifically admitted in the particular answer to each numbered paragraph in the Complaint, including but not limited to any allegation that may be contained in a header, subheader, or subpart

¹ For the avoidance of any doubt, each numbered paragraph of Sterigenics U.S.'s Answer corresponds to the numbered paragraph in the Complaint.

within the Complaint. Sterigenics U.S. also denies all allegations in the “Table of Contents” of Plaintiff’s Complaint.

Sterigenics U.S. provides this Answer based on a reasonable inquiry and its knowledge to-date. Investigation into the matters that are the subject of the Complaint are ongoing. Accordingly, Sterigenics U.S. reserves its right to amend, supplement, revise, clarify, or correct the responses set forth below.

1. Sterigenics U.S. admits that the Plaintiff has brought this lawsuit against Sterigenics U.S., Sotera Health, LLC, Sotera Health Holdings, LLC and Sotera Health Company. Sterigenics U.S. denies that it has caused the State of New Mexico any harm or damages or violated any law as alleged in the Complaint. Sterigenics U.S. denies that Plaintiff is entitled to any declaratory, injunctive or monetary relief in this case.

2. Sterigenics U.S. admits that it is and recognizes itself publicly as a global leader in comprehensive sterilization solutions meeting industrial sterilization needs in the medical device, pharmaceutical, advanced applications, commercial, and food industries. Except as expressly admitted, the allegations contained in Paragraph 2 are denied.

3. Sterigenics U.S. admits that it began operating its sterilization facility in Santa Teresa, New Mexico (the “Facility”) in 1989. Sterigenics U.S. admits that the Facility is a major medical products sterilization facility that is responsible for performing essential sterilizations of over 2.5 million medical products each year, including: custom surgical kits, preoperative skin preparation products, surgical drapes and gowns, cardiovascular tubing sets, internal powered surgical staplers, ophthalmic devices, Band-Aids, prefilled syringes, catheters, tubing for ear, nose, and throat, surgical diagnostic equipment, and tracheostomy-coiled-endotracheal tubes. Except as expressly admitted, the allegations contained in Paragraph 3 are denied, including but not limited

to any allegation that Sotera Health LLC, Sotera Health Holdings, LLC or Sotera Heath Company owned or operated the Facility.

4. Sterigenics U.S. admits that the Facility is located at 2400 Airport Road, Santa Teresa, New Mexico 88008. Except as expressly admitted, the allegations contained in Paragraph 4 are denied.

5. Sterigenics U.S. presently is without sufficient knowledge or information to form an opinion or belief as to the truth of the allegations in Paragraph 5 of the Complaint, which therefore stand denied.

6. Sterigenics U.S. admits that it has used ethylene oxide (“EtO”) in its sterilization operations at the Facility since the Facility began operations in 1989. Except as expressly admitted, the allegations contained in Paragraph 6 are denied.

7. Denied.

8. Sterigenics U.S. admits that in 1985 the U.S. Department of Health and Human Services’ (“HHS”) National Toxicology Program published a regulatory document titled, “Fourth Annual Report on Carcinogens” (the “Fourth Annual Report”), which stated that it was prepared as required by and “pursuant to Public Law 95-622.” Sterigenics U.S. admits that the Fourth Annual Report listed 148 substances as either “known carcinogens” or substances “which may reasonably be anticipated to be carcinogens.” Sterigenics U.S. admits that the Fourth Annual Report did not identify EtO as a “known carcinogen” and included instead EtO on a list of 119 substances “which may reasonably be anticipated to be carcinogenic,” which the Fourth Annual Report defined as “those for which there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.” Sterigenics U.S. admits in 2000 the HHS classified EtO as “known to be a carcinogen” in its Ninth Report on Carcinogens for the

purpose of HHS's regulatory requirements under 42 U.S.C. 241(b)(4). HHS has emphasized that "[a] listing in the Report does not by itself establish that a substance presents a cancer risk to an individual in daily life." Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory classifications, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 8 are denied, including but not limited to any allegation that the Fourth Annual Report or Ninth Annual Reports or any studies referenced therein evidence that any emission of EtO from the Facility evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

9. Denied.

10. Sterigenics U.S. admits only that the U.S. Environmental Protection Agency ("EPA") published a regulatory review titled, "Evaluation of the Inhalation of Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)," dated December 2016, ("IRIS") in which the EPA for the first time classified EtO as "carcinogenic to humans" according to the EPA's regulatory "2005 Guidelines for Carcinogen Risk Assessment." Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such a regulatory classification, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be

claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 10 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

11. Denied.

12. Sterigenics U.S. admits that IRIS increased its regulatory risk value for a continuous lifetime (24 hours a day for 70 years) of exposure to EtO to approximately 30 times its previous regulatory risk value for a continuous lifetime of exposure to EtO. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such a regulatory risk value, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 12 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

13. Sterigenics U.S. admits that IRIS included statements of certain regulatory “Inhalation Unit Risk Estimates” for a continuous lifetime (24 hours a day for 70 years) exposure to EtO. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such a regulatory risk estimate, which is in the nature of a

regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 13 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

14. Sterigenics U.S. admits that IRIS stated that it considered a human population study published by certain researchers at the National Institute for Occupational Safety and Health (“NIOSH”) and stated that “the evidence of carcinogenicity from human studies was deemed short of conclusive on its own.” Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of IRIS or the referenced study, which are in the nature of opinions, rather than factual matter capable of admission or denial in this Answer, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 14 are denied, including but not limited to any allegation that IRIS or the referenced study is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that they evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

15. Denied.

16. Denied.

17. Denied.

18. Denied.

19. Denied, including all subparts.

20. Sterigenics U.S. admits that the EPA and the New Mexico Environment Department (“NMED”) authorized Sterigenics U.S. to disconnect the Facility’s chamber backvents from the Facility’s abator emissions control system beginning in December 1997, because of the EPA’s safety concerns regarding certain explosion risks found at other EtO sterilization facilities in the United States. Sterigenics U.S. admits that it reconnected the backvents at the Facility for Chambers 8, 9, 10 and 13 to its abator emissions control system in 2013 and reconnected its backvents at the Facility for Chambers 1, 2, 3, 4, 5, 6, 7, 11 and 12 to the abator emissions control system in 2014. Sterigenics U.S. admits that the Facility has had very low levels of “fugitive” emissions of EtO, which has been known and authorized by the EPA and NMED. Except as expressly admitted herein, denied.

21. Sterigenics U.S. admits that on August 22, 2018, the EPA released an update to the National Air Toxics Assessment (“NATA Update”). Sterigenics U.S. admits that the EPA stated, “NATA is a *screening tool*, intended to help EPA and state, local and tribal air agencies determine if areas, pollutants or types of pollution sources need to be examined further to better understand risks to public health.” (emphasis in original). Sterigenics U.S. admits that the NATA Update stated that it involved 76,727 census tracts in the “50 U.S. states, Puerto Rico, the Virgin Islands, and the District of Columbia,” and included census tracts in Doña Ana County. Sterigenics U.S. admits that for each census tract identified, the NATA Update estimated a regulatory “cancer risk,” which the EPA defined as, “The probability of contracting cancer over the course of a lifetime, assuming continuous exposure (assumed in NATA to be 70 years).” Except as expressly admitted

herein, the allegations in Paragraph 21 are denied, including but not limited to any allegation that the NATA showed that “the residents of Santa Teresa and surrounding locations are at a statically significant increased risk of developing cancer,” that NATA is reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO, or that NATA evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

22. Sterigenics U.S. admits that, from 1996 through 2013, it voluntarily reported to EPA annual total EtO emissions from the Facility ranging from 641 lbs. to 10,082 lbs. Sterigenics U.S. admits that from 2014 to 2016, it reported to the EPA annual total EtO emissions from the Facility ranging from 967 lbs. to 5,761 lbs. Except as expressly admitted herein, the allegations in Paragraph 22 are denied.

23. Denied, including any allegation that the Facility’s EtO emissions have increased anyone’s risk of cancer in Doña Ana County.

24. Denied.

25. Denied.

26. Denied.

27. Denied.

28. Sterigenics U.S. admits that it has emitted EtO from the Facility as expressly authorized by and in compliance with environmental regulations and the Air Quality Permits the NMED has approved and issued during the history of the Facility’s operations. Sterigenics U.S. admits that it voluntarily reported following estimated amounts of EtO emissions permitted under its Air Quality Permits to the EPA from 1996 through 2016:

Year	Total Amount (lbs.)
1994	250
1995	300
1996	641
1997	1,137
1998	5,956
1999	5,318
2000	4,675
2001	5,044
2002	5,026
2003	6,752
2004	7,123
2005	11,756
2006	14,759
2007	14,022
2008	15,439
2009	11,485
2010	12,421
2011	13,068
2012	12,362
2013	10,082
2014	5,761

2015	1,003
2016	967

Sterigenics U.S. admits that it had emissions of EtO from the Facility in compliance with its NMED Air Quality Permits between the years 1989 and 1995. Except as expressly admitted herein, denied.

29. Denied.

30. Sterigenics U.S. states that it is without knowledge or information sufficient to form belief concerning the truth of the allegation that “the State’s presuit investigation included sampling of ambient outdoor air within a four-mile radius of the Santa Teresa Plant for EtO,” which therefore stands denied. Sterigenics U.S. denies the remaining allegations in Paragraph 30.

31. Sterigenics U.S. states that it is without knowledge or information sufficient to form belief concerning the truth of the allegations in Paragraph 31, which therefore stand denied.

32. Sterigenics U.S. states that it is without knowledge or information sufficient to form belief concerning the truth of the allegations in Paragraph 32, which therefore stand denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied, including but not limited to any allegation that the Facility’s EtO emissions have increased anyone risk of adverse health effects or diminished anyone’s property values.

37. Sterigenics U.S. admits that the State has filed this lawsuit. Otherwise, denied, including but not limited to any allegation that Defendants have engaged in any unlawful conduct or caused anyone any harm as alleged in the Complaint, and any allegation that Plaintiff is entitled to any relief that it seeks in this case.

38. Sterigenics U.S. admits that its Facility is located in New Mexico. Otherwise, denied.

39. Sterigenics U.S. admits that Defendants are foreign corporations and that venue for this case against Sterigenics U.S. in Doña Ana County is proper. Otherwise, denied.

40. Sterigenics U.S. admits that this Court has subject matter jurisdiction over this case.

41. Sterigenics U.S. admits that the Court has personal jurisdiction over Sterigenics U.S. in this case. Otherwise, denied.

42. Admitted.

43. Sterigenics U.S. admits that Attorney General Hector H. Balderas has filed this lawsuit in the name of the State of New Mexico. Otherwise, denied.

44. Sterigenics U.S. admits that NMSA 1978 Section 8-5-2 which sets forth “Duties of attorney general,” speaks for itself. Otherwise, denied.

45. Denied.

46. Denied, including but not limited to any allegation that Defendants have engaged in any misconduct alleged in the Complaint.

47. The allegations in Paragraph 47 of the Complaint are legal conclusions that do not require a response. To the extent that a response is required, Sterigenics U.S. admits that the New Mexico Unfair Practices Act states that the New Mexico Attorney General is authorized to enforce the New Mexico Unfair Practices Act. Sterigenics U.S. admits that New Mexico law authorizes the New Mexico Attorney General to bring a civil action to abate a public nuisance under New Mexico’s Public Nuisance Statute. Except as expressly admitted herein, denied, including but not limited to any allegation that Sterigenics U.S.’s Facility is a public nuisance or that Sterigenics U.S. has violated the New Mexico Unfair Practices Act.

48. Admitted.

49. Sterigenics U.S. admits that Sotera Health Holdings, LLC is a Delaware limited liability company with a principal place of business in Ohio. Except as expressly admitted herein, denied.

50. Sterigenics U.S. admits that Sotera Health LLC is a Delaware limited liability company that maintains its principal place of business in Ohio. Sterigenics U.S. further admits that Sotera Health LLC was formerly known as Sterigenics International LLC and Sterigenics International, Inc. Except as expressly admitted herein, denied.

51. Sterigenics U.S. admits that Sotera Health Company is a publicly held corporation listed on the NASDAQ exchange under ticker symbol SHC. Sterigenics U.S. admits that Sotera Health Company was incorporated in Delaware and has a principal place of business in Ohio. Sterigenics U.S. admits that Sotera Health Company is the indirect parent company of Sterigenics U.S. and Sotera Health LLC, and is the direct parent company of Sotera Health Holdings, LLC. Except as expressly admitted, denied.

52. Denied.

53. Sterigenics U.S. admits that EtO can be a gas at room temperature at atmospheric pressure. Sterigenics U.S. admits that EtO is colorless and can be flammable. Sterigenics U.S. denies that EtO is entirely odorless. Sterigenics U.S. admits that EtO is the only method that effectively sterilizes and does not damage numerous medical devices and products during the sterilization process, including but not limited to products that are sensitive to heat or moisture and cannot be sterilized by steam. Except as expressly admitted herein, denied.

54. Admitted.

55. Sterigenics U.S. admits that EtO does not persist in air or soil. Sterigenics U.S. admits that the EPA has said that EtO has an estimated half-life in air ranging from 69 (during summer months) to 149 days (during winter months). Sterigenics U.S. states that it is without information or knowledge sufficient to admit or deny the remainder of the second sentence of Paragraph 55, which therefore stands denied. Sterigenics U.S. admits that a World Health Organization (“WHO”) IARC Monograph on EtO has said, “The half-life of ethylene oxide in the atmosphere, assuming ambient concentrations of 5×10^5 hydroxy radicals/cm³, is 211 days. Data suggest that neither rain nor absorption into aqueous aerosols remove ethylene oxide from the atmosphere.” Except as expressly admitted herein, denied.

56. Sterigenics U.S. admits that EtO can be a gas at room temperature at atmospheric pressure. Sterigenics U.S. admits that EtO has a high vapor pressure and low boiling point. Except as expressly admitted herein, denied.

57. Sterigenics U.S. admits that EtO has a high vapor pressure. Sterigenics U.S. admits that EtO does not persist in soil, water or air. Except as expressly admitted herein, denied.

58. Sterigenics U.S. admits that EtO is heavier than air. Sterigenics U.S. admits that the World Health Organization has said that EtO “may travel along the ground; distant ignition possible.” Except as expressly admitted herein, denied.

59. Denied.

60. Denied.

61. Denied.

62. Sterigenics U.S. denies the allegations in Paragraph 62 as they relate to its sterilization facilities, including the Facility. Sterigenics U.S. is without knowledge or information

sufficient for it to admit or deny the truth of the allegations in Paragraph 62 with respect to facilities that it does not operate, which therefore stand denied.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Sterigenics U.S. admits that certain animal, bacteria and plant studies have reported that EtO has the potential to be genotoxic, damage DNA and be mutagenic in certain circumstances depending on the dose and duration of exposure. Except as expressly admitted herein, denied.

73. Sterigenics U.S. states that it presently is without information or knowledge sufficient to admit or deny the allegations in Paragraph 73, which therefore stand denied.

74. Sterigenics U.S. admits that in 1985 HHS's National Toxicology Program published its Fourth Annual Report, which stated that it was prepared as required by and "pursuant to Public Law 95-622." Sterigenics U.S. admits that the Fourth Annual Report listed 148 substances as either "known carcinogens" or substances "which may reasonably be anticipated to be carcinogens." Sterigenics U.S. admits that the Fourth Annual Report did not identify EtO as a "known carcinogen" and included instead EtO on a list of 119 substances "which may reasonably be anticipated to be carcinogenic," which the Fourth Annual Report defined as "those for which

there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.” Sterigenics U.S. admits in 2000 the HHS classified EtO as “known to be a carcinogen” in its Ninth Report on Carcinogens for the purpose of HHS’s regulatory requirements under 42 U.S.C. 241(b)(4). HHS has emphasized that “[a] listing in the Report does not by itself establish that a substance presents a cancer risk to an individual in daily life.” Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory classifications, which are in the nature of regulatory opinions, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 74 are denied, including but not limited to any allegation that the Fourth Annual Report or Ninth Annual Report or any studies referenced therein evidence that any emission of EtO from the Facility evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

75. Sterigenics U.S. admits only that in a 1994 “Monograph” the WHO characterized EtO as “carcinogenic to humans (Group 1)” according to the Monograph’s definition of “carcinogenic,” based on experimental animal studies and only “*limited evidence* in humans for the carcinogenicity of ethylene oxide.” (italics in original). Sterigenics U.S. lacks knowledge sufficient to form a belief as to the truth of the assertions in this Monograph, which are in the nature of opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Sterigenics U.S. further responds

that the WHO has stated that such a Monograph is only an evaluation of whether an agent is capable of causing cancer “under some circumstances,” and that the category “carcinogenic to humans (Group 1)” does not refer to the potency of an agent for causing cancer. Except as expressly admitted herein, the allegations in Paragraph 75 are denied, including but not limited to any allegation that this 1994 Monograph evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

76. Sterigenics U.S. admits that IRIS made the partially quoted statements in Paragraph 76 of the Complaint. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such statements, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 76 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

77. Sterigenics U.S. admits that in 1991 NIOSH published an article titled, “Mortality Among Workers Exposed to Ethylene Oxide” (the “1991 NIOSH Article”), which stated that it studied the occupational exposure of “18,254 workers at 14 plants producing sterilized medical supplied and spices.” Sterigenics U.S. lacks knowledge sufficient to form a belief as to the truth of the assertions in this article, which are in the nature of opinions rather than factual material

capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Sterigenics U.S. denies the remaining allegations in Paragraph 77, including but not limited to any allegation that the 1991 NIOSH Article evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

78. Sterigenics admits that IRIS stated, “Although the evidence of carcinogenicity from human studies was deemed short of conclusive on its own, EtO is characterized as ‘carcinogenic to humans’ by the inhalation route of exposure based on the total weight of evidence, in accordance with the U.S. Environmental Protection Agency’s (EPA’s) 2005 *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a).” Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of this statement, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 78 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

79. Denied.

80. Sterigenics U.S. admits that IRIS said that its confidence in its regulatory “hazard characterization of EtO as ‘carcinogenic to humans’ is high.” Sterigenics U.S. lacks sufficient

knowledge or information to form a belief as to the truth of the scientific or medical accuracy of that statement, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 80 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

81. Sterigenics U.S. admits that the EPA made the regulatory statement in IRIS that EtO is carcinogenic to humans for the first time in December 2016. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of that regulatory classification, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 81 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

82. Sterigenics U.S. admits that IRIS was an EPA regulatory evaluation of the carcinogenicity of EtO. Sterigenics U.S. admits that IRIS stated that “in accordance with the U.S. Environmental Protection Agency’s (EPA’s) Guidelines for Carcinogen Risk Assessment,” it characterized EtO as ““carcinogenic to humans”” and said that a “mutagenic mode of action is operative in EtO carcinogenicity.” Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such statements, which is in the nature of regulatory opinions, rather than factual matter capable of admission or denial in this Answer, and further, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 82 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

83. Denied.

84. Sterigenics U.S. admits that IRIS increased its regulatory risk value for a continuous lifetime (24 hours a day for 70 years) of exposure to EtO to approximately 30 times its previous regulatory risk value for a continuous lifetime of exposure to EtO. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of that regulatory risk estimate, which is in the nature of a regulatory opinion, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly

admitted herein, the allegations in Paragraph 84 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

85. Denied.

86. Denied.

87. Sterigenics U.S. admits that it began its sterilization operations using EtO at the Facility in 1989. Sterigenics U.S. states that it has safely emitted low levels of EtO from its sterilization operations in compliance with environmental regulations and its Air Quality Permits issued by the NMED during the Facility's existence. Except as expressly admitted herein, denied.

88. Sterigenics U.S. admits that, in August 1977, the NIOSH issued a "Special Occupational Hazard Review with Control Recommendations" for the "Use of Ethylene Oxide as a Sterilant in Medical Facilities."

89. Sterigenics U.S. admits that NIOSH's August 1977 "Special Occupational Hazard Review with Control Recommendations" for the "Use of Ethylene Oxide as a Sterilant in Medical Facilities" stated, "Ethylene oxide (ETO) is used extensively within health care facilities for sterilization of equipment and supplies which are heat sensitive. It is unique for this purpose. Alternative chemicals or processes have, in themselves, serious limitations or health hazards. NIOSH recognizes, therefore, that the continued use of ETO as a gaseous sterilant is highly desirable in many situations. Recent results of tests for mutagenesis have increased the concern for potential health hazards associated with exposure to ETO. In order to assess the potential for exposure and hazards, NIOSH has undertaken this Special Occupational Hazard Review."

Sterigenics U.S. lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of regulatory opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sterigenics U.S. denies the allegations in Paragraph 89, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

90. Sterigenics U.S. admits that NIOSH's August 1977 "Special Occupational Hazard Review with Control Recommendations" for the "Use of Ethylene Oxide as a Sterilant in Medical Facilities" makes the statement quoted in Paragraph 90 of the Complaint. Sterigenics U.S. lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sterigenics U.S. denies the allegations in Paragraph 90, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

91. Sterigenics U.S. admits that NIOSH's August 1977 "Special Occupational Hazard Review with Control Recommendations" for the "Use of Ethylene Oxide as a Sterilant in Medical

Facilities” stated, “No definitive epidemiological studies, and no standard long-term carcinogenesis assays, are available on which to assess carcinogenic potential. Limited tests by skin application or subcutaneous injections in mice did not reveal carcinogenicity. However, the alkylating and mutagenic properties of ETO are sufficient bases for concern about its potential carcinogenicity.” Sterigenics U.S. lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sterigenics U.S. denies the allegations in Paragraph 91, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

92. Sterigenics U.S. admits that, after recognizing that “[n]o definitive epidemiological studies, and no standard long-term carcinogenesis assays, are available on which to assess carcinogenic potential. Limited tests by skin application or subcutaneous injections in mice did not reveal carcinogenicity,” NIOSH’s August 1977 “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical Facilities” said that “the alkylating and mutagenic properties of ETO are sufficient bases for concern about its potential carcinogenicity” and recommended that “EtO be considered as mutagenic and potentially carcinogenic to humans, and that occupational exposure to be minimized” Sterigenics U.S. lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature

of opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sterigenics U.S. denies the allegations in Paragraph 92, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

93. Denied.

94. Sterigenics U.S. admits that NIOSH's August 1977 "Special Occupational Hazard Review with Control Recommendations" for the "Use of Ethylene Oxide as a Sterilant in Medical Facilities" stated its regulatory opinion that reasons for unnecessary occupational exposure of persons working in sterilization facilities to EtO includes "inadequate ventilation of sterilizers," "poor design of the sterilization facility." Sterigenics U.S. lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of a regulatory opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sterigenics U.S. denies the allegations in Paragraph 94, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

95. Sterigenics U.S. admits that, in May 1981, NIOSH released Current Intelligence Bulletin 35, entitled “Ethylene Oxide (EtO): Evidence of Carcinogenicity,” in which NIOSH “recommend[ed] that ethylene oxide be regarded in the workplace as a potential occupational carcinogen, and that appropriate controls be used to reduce worker exposure.” Sterigenics U.S. lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of a regulatory opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sterigenics U.S. denies the allegations in Paragraph 95, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

96. Sterigenics U.S. admits that in 1985 the HHS National Toxicology Program published its Fourth Annual Report, which is a regulatory document that stated that it was prepared as required by and “pursuant to Public Law 95-622.” Sterigenics U.S. admits that the Fourth Annual Report listed 148 substances as either “known carcinogens” or substances “which may reasonably be anticipated to be carcinogens.” Sterigenics U.S. admits that the Fourth Annual Report did not identify EtO as a “known carcinogen” and included instead EtO on a list of 119 substances “which may reasonably be anticipated to be carcinogenic,” which the Fourth Annual Report defined as “those for which there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.” Sterigenics U.S. admits that in 1987 California Proposition 65 included EtO on its list of chemicals that it said cause cancer, for

regulatory purposes. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory classifications, which are in the nature of regulatory opinions, rather than factual matter capable of admission or denial in this Answer, and further, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 96 are denied, including but not limited to any allegation that the Fourth Annual Report or California Proposition 65 evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

97. Sterigenics U.S. admits that it operated two sterilization facilities using EtO in California in 1987 and that it was aware that EtO was regulated under California Proposition 65 in 1987. Except as expressly admitted herein, the allegations in Paragraph 97 are denied, including but not limited to any allegation that Sotera Health LLC, Sotera Health Holdings, LLC or Sotera Health Company operated sterilization facilities in California and that California Proposition 65 evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

98. Sterigenics U.S. admits that the 1991 NIOSH Article stated that it studied the occupational EtO exposure of “18,254 workers at 14 plants producing sterilized medical supplied and spices.” Sterigenics U.S. admits that workers at its Willowbrook, IL sterilization facility were included among the workers in the study. Sterigenics U.S. lacks knowledge sufficient to form a belief as to the truth of the assertions in the 1991 NIOSH Article, which are in the nature of opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or

liability that may be claimed to arise therefrom. Sterigenics U.S. denies the remaining allegations in of Paragraph 98, including but not limited to any allegation that the 1991 NIOSH Article evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

99. Denied.

100. Sterigenics U.S. admits that Kathy Hoffman sent the EPA's Science Advisory Board a letter dated November 12, 2014. Sterigenics U.S. admits that Ms. Hoffman was Sterigenics U.S.'s Senior Vice President of Global Environmental, Health & Safety at the time of sending this letter. Except as expressly admitted herein, denied.

101. Denied as stated.

102. Denied.

103. Sterigenics U.S. admits that IRIS relied on NIOSH studies and categorized EtO as "carcinogenic to humans" for regulatory purposes for the first time in December 2016. Sterigenics U.S. lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory positions, which is in the nature of regulatory opinions, rather than factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sterigenics U.S. denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 103 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

104. Denied as stated.

105. Sterigenics U.S. admits that Jeffrey Shuren, as director of the FDA's Center for Devices and Radiological Health, sent Rick Keigwin, Director of the Office of Pesticide Programs of the EPA, a February 5, 2020 letter in response to outreach from the EPA. Sterigenics U.S. admits that Jeffrey Shuren's February 5, 2020 letter stated, "EPA should establish EtO emissions limits based on the levels necessary to protect human health and the environment from EtO toxicity." Except as expressly admitted, denied.

106. Sterigenics U.S. admits that Jeffrey Shuren's February 5, 2020 letter referenced in Paragraph 105 of the Complaint stated, "Today, about fifty percent of all sterile medical devices in the U.S. are sterilized with EtO" and "FDA looks to EPA to set allowable limits for EtO emissions since FDA does not have the authority to do so. Contract sterilizers and medical device manufacturers must comply with the EtO standards and guidelines that EPA sets and FDA is committed to working with these entities to reduce the amount of EtO used and to explore the use of alternatives as appropriate. If a facility is unable to meet EPA emissions limits and its inability to do so could lead to product availability concerns, FDA will work with the facility and other entities in the supply chain to mitigate these concerns." Except as expressly admitted, denied.

107. Denied.

108. Denied.

109. Sterigenics U.S. admits that its Facility is located in a remote industrial area that is approximately 2 miles from the nearest school or neighborhood and approximately 2.5 miles from the nearest church. Sterigenics U.S. states that it is without information or knowledge sufficient to admit or deny the truth of the remaining allegations in Paragraph 109, which therefore stand denied.

110. Sterigenics U.S. admits that the Facility emitted the following estimated amounts of EtO emissions in compliance with environmental regulations and its Air Quality Permits from the NMED from 1996 through 2016:

Year	Total Amount (lbs.)
1994	250
1995	300
1996	641
1997	1,137
1998	5,956
1999	5,318
2000	4,675
2001	5,044
2002	5,026
2003	6,752
2004	7,123
2005	11,756
2006	14,759
2007	14,022
2008	15,439
2009	11,485
2010	12,421
2011	13,068

2012	12,362
2013	10,082
2014	5,761
2015	1,003
2016	967

Sterigenics U.S. admits that it had emissions of EtO from the Facility in compliance with its NMED Air Quality Permits between the years 1989 and 1995 and from 2017 to present. Except as expressly admitted herein, denied, including allegation that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

111. Sterigenics U.S. admits that it voluntarily reported the Facility's estimated EtO emissions under its Air Quality Permits to the EPA from at least 1995 to 2016. Sterigenics U.S. admits that it has not reported estimates of the Facility's low level EtO emissions to the EPA's Toxics Release Inventory program from 2017 to present and that such reporting is not required by the EPA. Except as expressly admitted herein, denied.

112. Denied.

113. Sterigenics U.S. admits that it voluntarily reported to the EPA the following estimated amounts of EtO emissions from the Facility under its Air Quality Permits from the NMED from 1994 through 2016:

Year	Total Amount (lbs.)
1994	250
1995	300

1996	641
1997	1,137
1998	5,956
1999	5,318
2000	4,675
2001	5,044
2002	5,026
2003	6,752
2004	7,123
2005	11,756
2006	14,759
2007	14,021
2008	15,439
2009	11,485
2010	12,421
2011	13,069
2012	12,362
2013	10,082
2014	5,761
2015	1,003
2016	967

Sterigenics U.S. states that it has been unable to locate records regarding reporting of the Facility's EtO emissions to the EPA for the years 1994 and 1995 and therefore presently does not have information or knowledge sufficient to enable it to admit or deny the allegations in Paragraph 113 with respect to those years. Except as expressly admitted herein, denied.

114. Sterigenics U.S. admits that fugitive emissions from the Facility were very low amounts. Except as expressly admitted herein, denied.

115. Denied.

116. Sterigenics admits that records reflect the following estimated amounts of EtO were used at the Facility in the years shown:

Period	Amount (lbs.)
1996	405,875
1997	442,726
1998	446,895
1999	399,064
2000	391,918
2001	422,823
2002	421,340
2003	541,784
2004	606,964
2005	771,087
2006	968,009
2007	919,635

2008	1,012,606
2009	1,035,160
2010	1,001,320
2011	1,055,102
2012	1,128,330
2013	1,034,298
2014	1,010,601
2015	1,008,672
2016	1,015,733
2017	998,570
2018	1,086,463
2019	1,092,940
2020	1,089,769

Except as expressly admitted herein, denied.

117. Sterigenics U.S. admits that the EPA and NMED authorized Sterigenics U.S. to disconnect the Facility's chamber backvents from the Facility's abator emissions control system beginning in December 1997, because of the EPA's safety concerns regarding certain explosion risks found at other EtO sterilization facilities in the United States. Sterigenics U.S. admits that it reconnected the backvents for Chambers 8, 9, 10 and 13 to its abator emissions control system in 2013 and reconnected its backvents for Chambers 1, 2, 3, 4, 5, 6, 7, 11 and 12 to the abator emissions control system in 2014. Sterigenics U.S. admits that during the time when the Facility's backvents were not routed to the Facility's abator emission control system pursuant to the EPA's

authorization, the Facility had very low levels of “fugitive” emissions of EtO from the Facility, which was known and authorized by the EPA and NMED. Except as expressly admitted herein, denied.

118. Sterigenics U.S. states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 118 that a “former Sterigenics employee” told Plaintiff what is alleged in Paragraph 118, which therefore stands denied. Sterigenics U.S. denies the remaining allegations in Paragraph 118.

119. Denied.

120. Denied.

121. Sterigenics U.S. states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 121 that a “former Sterigenics employee” told Plaintiff what is alleged in Paragraph 121, which therefore stands denied. Sterigenics U.S. denies the remaining allegations in Paragraph 121.

122. Sterigenics U.S. states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 122 that a “former employee” indicated to Plaintiff what is alleged in Paragraph 122, which therefore stands denied. Sterigenics U.S. denies the remaining allegations in Paragraph 122.

123. Sterigenics U.S. states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 123 that a “former Sterigenics employee” indicated to Plaintiff what is alleged in Paragraph 123, which therefore stands denied. Sterigenics U.S. denies the remaining allegations in Paragraph 123.

124. Denied.

125. Denied.

126. Denied.

127. Sterigenics U.S. admits that on August 22, 2018, the EPA released the NATA Update. Except as expressly admitted herein, denied.

128. Denied.

129. Sterigenics U.S. admits that the NATA update used emissions data from 2014. Except as expressly admitted herein, denied.

130. Sterigenics U.S. admits that it voluntarily reported to the EPA the following estimated amounts of EtO emissions from the Facility for 2011 through 2014:

Year	Total Amount (lbs.)
2011	13,068
2012	12,362
2013	10,082
2014	5,761

Except as expressly admitted herein, denied.

131. Denied.

132. Denied.

133. Sterigenics U.S. admits that in 2014 the Facility emitted an estimated 5,761 lbs. of EtO and voluntarily reported those estimated emissions to the EPA. Sterigenics U.S. admits that 5,761 lbs. is 2.8805 tons. Sterigenics U.S. denies the remaining allegations in Paragraph 133 and its subparts.

134. Denied.

135. Denied.

136. Sterigenics U.S. states that it presently is without information or knowledge sufficient to admit or deny the allegations in Paragraph 136 of the Complaint, which therefore stand denied.

137. Sterigenics U.S. states that it presently is without information or knowledge sufficient to admit or deny the allegations in Paragraph 137 of the Complaint, which therefore stand denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Sterigenics U.S. admits that the NMED issued Sterigenics U.S. an Air Quality Permit for the Facility in 1989. Sterigenics U.S. admits that the NMED issued modifications to the Facility's Air Quality Permit. Sterigenics U.S. admits that the NMED Air Quality Permits and Air Quality Permit modifications included emissions authorizations, reporting requirements, emissions control approvals and requirements, and other requirements and approvals. Except as expressly admitted herein, denied.

146. Denied.

147. Denied, including all subparts.

148. Denied.

149. Denied.

150. Sterigenics U.S. admits that it has contracts with its sterilization customers who pay Sterigenics U.S. for its sterilization services. Except as expressly admitted herein, denied.

151. Sterigenics U.S. admits that it has publicly acknowledged and explained that its EtO sterilization operations are safe to the environment and others. Except as expressly admitted herein, denied.

152. Sterigenics U.S. admits that its environmental policy, as stated on its website, is that it is “dedicated to protecting the environment and our communities. Our facilities adhere to Environmental Management Systems (EMS) of established requirements and standards. We focus on continuous improvements and eliminating risk to protect people, the environment, and property. Our EMS meet or exceed compliance requirements set by our regulators.” Except as expressly admitted herein, denied.

153. Sterigenics U.S. admits that the Sotera Health 2017 Global Health Corporate Sustainability and Social Responsibility Report includes the recognitions partially quoted in Paragraph 153.

154. Sterigenics U.S. admits that it has recognized and informed the public of the fact that its sterilization facilities using EtO are safe for the environment.

155. Sterigenics U.S. admits that its website states its Unwavering Commitment to Safety and the Environment. Sterigenics U.S. admits that its website has at times between August 2014 and February 2018 contained the statements partially quoted in Paragraph 155 of the Complaint. Except as expressly admitted herein, denied.

156. Sterigenics U.S. admits that it stated its commitment to safety and the environment on its website as partially quoted in Paragraph 155 of the Complaint and in other public statements

recognizing that commitment to inform the public of that commitment to safety and the environment by Sterigenics U.S. Except as expressly admitted herein, denied.

157. Denied.

158. Denied.

FIRST CAUSE OF ACTION
PUBLIC NUISANCE

159. Sterigenics U.S. incorporates by reference its responses to Paragraphs 1 through 158 of the Complaint as if stated fully herein.

160. Paragraph 160 states legal conclusions to which a response is not required. To the extent a response is required, denied.

161. Denied.

162. Denied.

163. Denied.

164. Denied.

165. Denied.

166. Denied, including but not limited any allegation that its Facility's permitted and safe emissions of EtO are toxic, endangering anyone's health or degrading the quality of air.

167. Denied.

168. Denied, including but not limited to any allegation that the Facility has harmed New Mexico's rights or interests or caused New Mexico any inconvenience.

169. Denied.

170. Denied.

171. Denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

176. Denied.

177. Sterigenics U.S. denies that its Facility has caused any medical disorders and denies that Plaintiff is entitled to the order and monitoring program it seeks in Paragraph 177 of the Complaint.

178. Denied.

SECOND CAUSE OF ACTION
VIOLATIONS OF THE NEW MEXICO PUBLIC NUISANCE STATUTE,
NMSA 1978 §§ 30-8-1, *ET SEQ.*

179. Sterigenics U.S. incorporates by reference its responses to Paragraphs 1 through 178 of the Complaint as if stated fully herein.

180. Paragraph 180 states legal conclusions to which a response is not required. To the extent a response is required, denied.

181. Paragraph 180 states legal conclusions to which a response is not required. To the extent a response is required, Sterigenics U.S. states that Plaintiff has included asserted a purported claim under New Mexico' public nuisance statute but denies that Plaintiff has stated a claim for a violation of the statute in this case.

182. Sterigenics U.S. admits that NMSA 30-8-1 states, "A public nuisance consists of knowingly creating, performing or maintain anything affecting any number of citizens without lawful authority which is either: A. injurious to public health, safety, morals or welfare; or B. interferes with the exercise and enjoyment of public rights, including the right to us public property. Whoever commits a public nuisance for which the act or penalty is not otherwise prescribed by law is guilty of a petty misdemeanor." Except as expressly admitted herein, denied.

183. Sterigenics U.S. admits that New Mexico law authorizes the New Mexico Attorney General to bring a civil action to abate a public nuisance under New Mexico's Public Nuisance Statute. Except as expressly admitted herein, denied, including but not limited to any allegation that Sterigenics U.S.'s Facility is a public nuisance or that Sterigenics U.S. has violated New Mexico's Public Nuisance Statute.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

188. Denied.

189. Denied.

190. Denied, including but not limited to any allegation that its Facility's permitted and safe emissions of EtO are toxic, endangering anyone's health or degrading the quality of air.

191. Denied.

192. Denied, including but not limited to any allegation that the Facility has harmed New Mexico's rights or interests or caused New Mexico any inconvenience.

193. Denied.

194. Denied.

195. Denied.

196. Denied.

197. Denied.

198. Denied.

199. Denied.

200. Denied.

201. Sterigenics U.S. denies that its Facility has caused any medical disorders and denies that Plaintiff is entitled to the order and monitoring program it seeks in Paragraph 201 of the Complaint.

202. Denied.

THIRD CAUSE OF ACTION
STRICT LIABILITY

203. Sterigenics U.S. incorporates by reference its responses to Paragraphs 1 through 202 of the Complaint as if stated fully herein.

204. Denied.

205. Denied.

206. Denied.

207. Denied.

208. Denied.

209. Denied.

210. Denied.

211. Denied.

212. Denied.

FOURTH CAUSE OF ACTION
NEGLIGENCE

213. Sterigenics U.S. incorporates by reference its responses to Paragraphs 1 through 212 of the Complaint as if stated fully herein.

214. Denied.

215. Denied.

216. Denied.

217. Denied.

218. Sterigenics U.S. denies that its permitted emissions of EtO are toxic and any allegation that it breached a legal duty to anyone in this case.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

FIFTH CAUSE OF ACTION
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

223. Sterigenics U.S. incorporates by reference its responses to Paragraphs 1 through 222 of the Complaint as if stated fully herein.

224. Denied.

225. Denied.

226. Denied.

227. Denied.

228. Denied

229. Denied

230. Denied

231. Denied.

SIXTH CAUSE OF ACTION
**VIOLATIONS OF NEW MEXICO UNFAIR PRACTICES ACT,
1978 NMSA §§ 57-12-1, *ET SEQ.***

232. Sterigenics U.S. incorporates by reference its responses to Paragraphs 1 through 231 of the Complaint as if stated fully herein.

233. Denied.

234. Admitted.

235. Sterigenics U.S. admits that NMSA §§57-12-2(D) says, “‘unfair or deceptive trade practice’ means an act specifically declared unlawful pursuant to the Unfair Practices Act, a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services or in the extension of credit or in the collection of debts by a person in the regular course of the person’s trade or commerce, that may, tends to or does deceive or mislead any person and includes” the acts specifically enumerated in NMSA § 57-12-2(D). Except as expressly admitted herein, denied.

236. Sterigenics U.S. admits that NMSA § 57-12-2(D) defines an unfair or deceptive trade practice to include, “if made in connection with the sale, lease, rental or loan of goods or services,” “representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that the person does not have,” “representing that goods or services are of a particular standard, quality or grade or that goods are of a particular style or model if they are of another” and “using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if doing so deceives or tends to deceive.” Except as expressly admitted herein, denied.

237. Denied.

238. Denied.

239. Denied.

240. Denied.

241. Denied.

242. Denied.

243. Denied.

244. Sterigenics U.S. denies that Plaintiff is entitled to any relief that it seeks in Paragraph 244 of the Complaint.

Sterigenics U.S. denies that Plaintiff is entitled to any relief requested in Plaintiff's prayer for relief.

Except as expressly and specifically admitted herein, Sterigenics U.S. denies the allegations set forth in Plaintiff's Complaint.

DEFENSES

Without admitting or acknowledging that Sterigenics U.S. bears the burden of proof as to any of them, Sterigenics U.S. asserts the following defenses:

FIRST DEFENSE

The Complaint and each cause of action contained therein fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Plaintiff has failed to provide a reasonable statement of a claim for relief against Sterigenics U.S. Sterigenics U.S. does not have reasonable notice of the time, place, nature, and manner of the claimed wrongs by Sterigenics U.S. as they relate to Plaintiff's alleged damages. Therefore, Plaintiff has failed to state a claim against Sterigenics U.S. upon which relief can be granted.

THIRD DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

FOURTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, *res*

judicata, laches, and unclean hands.

FIFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Sterigenics U.S. has acted reasonably, in good faith, and with the skill, prudence, and diligence exercised by others.

SIXTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Sterigenics U.S. did not owe or breach any legal duty to Plaintiff as alleged in the Complaint.

SEVENTH DEFENSE

Plaintiff's claims may be preempted or barred, in whole or in part, expressly or impliedly, by state and federal law and regulations, including but not limited to the Federal Food, Drug and Cosmetic Act and the Medical Device Amendments of 1976, *e.g.*, 21 U.S.C. §§ 337(a), 360k(a), the Clean Air Act, 42 U.S.C. § 7401 *et seq.*, and the New Mexico Air Quality Control Act, and their implementing regulations, along with any state and federal air quality permits for regulated air emissions.

EIGHTH DEFENSE

Any EtO emitted at Sterigenics U.S.'s facility in connection with its sterilization of medical products was emitted as authorized by and in conformity with the applicable laws and regulations, prevailing state of the art standards, and prevailing standards of the industry.

NINTH DEFENSE

Any emissions of EtO by Sterigenics U.S., as authorized by both state and federal regulators, are not properly the subject of a public nuisance claim.

TENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the sterilization of medical

products using EtO is not an “ultrahazardous and/or abnormally dangerous activity” as alleged in the Complaint.

ELEVENTH DEFENSE

Plaintiff’s claims are barred, in whole or in part, because the social utility and benefit of the sterilization of medical products with EtO outweighs any risk of danger and/or harm, if any.

TWELFTH DEFENSE

At all times material to Plaintiff’s claims, the state of medical and scientific knowledge did not provide Sterigenics U.S. with either knowledge or reason to know of a foreseeable risk of harm to Plaintiff stemming from Sterigenics U.S.’s sterilization facility.

THIRTEENTH DEFENSE

There is a lack of joinder of one or more parties who should or must be joined in this action.

FOURTEENTH DEFENSE

Plaintiff’s claims are barred, in whole or in part, because Plaintiff’s injuries, if any, were the result of actions or circumstances, or persons, entities, or conditions, unforeseeable to Sterigenics U.S. and beyond its control.

FIFTEENTH DEFENSE

Any putative claims available to Plaintiff but not joined in this action are barred for failure to assert those claims in the Complaint.

SIXTEENTH DEFENSE

No injury or damage allegedly suffered by Plaintiff, if any, was legally or proximately caused by any alleged act or omission on the part of Sterigenics U.S..

SEVENTEENTH DEFENSE

Sterigenics U.S. pleads its rights to contribution and/or indemnity.

EIGHTEENTH DEFENSE

Sterigenics U.S. denies that it has any liability to Plaintiff; but, to the extent that Plaintiff can or has failed to avail themselves of funds from unnamed third parties, including, without limitation insurance companies and unnamed potentially responsible parties, Sterigenics U.S. may be entitled to a set-off in the amount of such funds including interest.

NINETEENTH DEFENSE

Plaintiff's claims may be barred, in whole or in part, to the extent that it has released, settled, entered into an accord and satisfaction, or otherwise compromised the causes of action in their Complaint.

TWENTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent that the injuries alleged were caused by the acts or omissions of a third party and not Sterigenics U.S.

TWENTY-FIRST DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent that the acts and/or omissions of persons or entities other than Sterigenics U.S., over whom Sterigenics U.S. had no control, were intervening or superseding causes of the injuries alleged by Plaintiff.

TWENTY-SECOND DEFENSE

Any claim that liability for any of Plaintiff's alleged injuries and damages should be based upon a concert of action, enterprise liability or market share liability theory is contrary to the fact that such theories are not recognized under the law of this jurisdiction and, if applied by the Court here, would deny Sterigenics U.S. its rights of equal protection of the law and due process of law.

TWENTY-THIRD DEFENSE

Plaintiff has not suffered any injury in order to assert or recover on the causes of action in the Complaint.

TWENTY-FOURTH DEFENSE

If Plaintiff sustained any injury or damage, which Sterigenics U.S. denies, then such injury or damage was proximately caused or contributed to by other factors and not by EtO used to sterilize medical equipment at Sterigenics U.S.'s facility.

TWENTY-FIFTH DEFENSE

If Plaintiff sustained any injury or damage as a result of EtO in the atmosphere, which Sterigenics U.S. denies, then such injury or damage was caused by EtO from sources other than emissions attributable to Sterigenics U.S.'s facility, including but not limited to, endogenously produced EtO.

TWENTY-SIXTH DEFENSE

Plaintiff's claims may be barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitation of awards, caps on recovery, and set-offs.

TWENTY-SEVENTH DEFENSE

Plaintiff's claim for punitive damages fails as a matter of law.

TWENTY-EIGHTH DEFENSE

Plaintiff is not entitled to punitive damages because no act or omission of Sterigenics U.S. shows malice, willfulness, recklessness, wantonness, fraud, or bad faith.

TWENTY-NINTH DEFENSE

Sterigenics U.S. may not be found liable for punitive damages where the conditions which form the basis of Plaintiff's claims are, and have been, the subject of state or federal regulatory

action or oversight, and when there has been substantial compliance with the findings, orders, and directives of the responsible regulatory agency.

THIRTIETH DEFENSE

Plaintiff's claim for punitive damages is barred in whole or in part by applicable state and federal law.

THIRTY-FIRST DEFENSE

Plaintiff's claim for punitive damages is barred by the Due Process Clause and Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution, the prohibition of excessive fines contained in the Eighth Amendment to the U.S. Constitution, and the Double Jeopardy Clause of the Fifth Amendment.

THIRTY-SECOND DEFENSE

Plaintiff's claim for punitive damages is barred by Article II, Section 18 of the Constitution of the State of New Mexico, which guarantees that no person shall be deprived of life, liberty, or property without due process of law; Article II, Section 4 of the Constitution of the State of New Mexico, which guarantees that no person shall be denied the equal protection of the laws; and Article II, Section 13 of the Constitution of the State of New Mexico, which prohibits the imposition of excessive fines.

THIRTY-THIRD DEFENSE

Plaintiff's claim for punitive damages is barred because any actions and operations alleged in this case complied with all relevant and applicable federal and state laws and regulations and with industry customs and standards.

THIRTY-FOURTH DEFENSE

Plaintiff's claim for punitive damages is barred because Sterigenics U.S. lacked notice that its conduct could subject it to punishment.

THIRTY-FIFTH DEFENSE

Plaintiff's claim for punitive damages is preempted by federal law.

THIRTY-SIXTH DEFENSE

Plaintiff's claims for special damages are barred because they are not specifically stated or pled with particularity, and Plaintiff cannot prove the required elements to recover such damages.

THIRTY-SEVENTH DEFENSE

There is no statute providing for Plaintiff's strict liability claim and, therefore, said claim fails to state a claim upon which relief can be granted.

THIRTY-EIGHTH DEFENSE

Plaintiff's strict liability claim is barred as a matter of law because such a claim based on the allegations in the Complaint has not been recognized by New Mexico law.

THIRTY-NINTH DEFENSE

Plaintiff's Unfair Practices Act claim is barred as a matter of law because such a claim based on the allegations in the Complaint is not actionable under the New Mexico Unfair Practices Act.

FORTIETH DEFENSE

To the extent not incorporated above, Sterigenics U.S. raises all affirmative defenses applicable under New Mexico law.

RESERVATION OF DEFENSES

Sterigenics U.S. hereby gives notice that it intends to rely upon such other defenses that are or may become available or apparent during the course of discovery and reserves the right to add or amend these defenses as discovery proceeds.

DEMAND FOR TWELVE-PERSON JURY

Sterigenics U.S. by and through the undersigned counsel, and pursuant to N.M. R. Civ. P. Dist. Ct. 1-038, hereby demands a trial by jury of twelve competent and impartial jurors be had on all triable issues in this case.

WHEREFORE, having answered Plaintiff's Complaint as specified herein, Sterigenics U.S. prays as follows:

- (a) Judgment in its favor on each and every Count contained in Plaintiff's Complaint;
- (b) That Plaintiff take nothing by reason of its Complaint;
- (c) That all costs of the action, including reasonable attorneys' fees, be taxed upon Plaintiff;
- (d) That a trial by a jury of twelve be had on all triable issues in this case; and
- (e) That this Court grant Sterigenics U.S. such other and further relief as the Court deems just, equitable, and proper.

[signature on following page]

Signed this 26th day of January, 2022.

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

By: /s/ Alex C. Walker

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WE HEREBY CERTIFY that a true
and correct copy of the foregoing was
submitted through the Odyssey
Electronic Filing System for filing and
service to all counsel of record this 26th
day of January, 2022.

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

By: /s/ Alex Walker

Alex C. Walker